IN THE MATTER OF

\* BEFORE THE

**ALCO PHARMACY** 

\* MARYLAND BOARD

PERMIT No: PW0249

\* OF PHARMACY

Respondent

\* Case No.: PI-15-159

\* \* \* \* \* \* \* \* \* \* \*

# **CONSENT ORDER**

On March 24, 2017, the Maryland State Board of Pharmacy (the "Board") charged **ALCO PHARMACY, permit number: PW0249** ("the Respondent-Pharmacy"), under the Maryland Pharmacy Act (the "Act"), Md. Code Ann., Health Occ. II ("Health Occ. II"), §§ 12-101 *et seq.* (2014 Repl. Vol. and 2016 Supp.) and the Code of Maryland Regulations ("COMAR").

The Board charged the Respondent-Pharmacy with violating the following provisions of the Act:

## § 12-403. Required standards.

. . .

- (c) In general Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:
  - (1) Shall be operated in compliance with the law and with the rules and regulations of the Board;

\* \* \*

(9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under 12-313 or a registered pharmacy technician under 12-6B-09 of this title;

. . .

(12) Shall store all prescriptions or nonprescription drugs or devices properly and safely subject to the rules and regulations adopted by the Board; [and/or]

.....

(19) May not allow an unauthorized individual to represent that the individual is a pharmacist, a registered pharmacy intern, or registered pharmacy technician[.]

# § 12-313. Denials, reprimands, suspensions, and revocations—Grounds

- (b) In general Subject to the hearing provisions of § 12-315 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may reprimand any licensee, place any licensee on probation, or suspend or revoke a license of a pharmacist if the licensee:
  - (3) Aids an unauthorized individual to practice pharmacy or to represent that the individual is a pharmacist or a registered pharmacy technician;
  - (4) Delegates pharmacy acts to an unauthorized individual; [and/or]
  - (25) Violates any rule or regulation adopted by the Board[.]

The Board also charged the Respondent-Pharmacy with violating the following COMAR provisions:

# COMAR 10.34.10.01. Pharmacist Code of Conduct—Patient Safety and Welfare.

#### A. A pharmacist shall:

- (1) Abide by all federal and State laws relating to the practice of pharmacy and the dispensing, distribution, storage, and labeling of drugs and devices, including but not limited to:
  - (a) United States Code. Title 21,
  - (b) Health-General Article, Titles 21 and 22, Annotated Code of Maryland,
  - (c) Health Occupations Article, Title 12, Annotated Code of Maryland,
  - (d) Criminal Law Article, Title 5, Annotated Code of Maryland, and
  - (e) COMAR 10.19.03.

### B. A pharmacist may not:

- (1) Engage in conduct which departs from the standard of care ordinarily exercised by a pharmacist;
- (2) Practice pharmacy under circumstances or conditions which prevent the proper exercise of professional judgment; or
- (3) Engage in unprofessional conduct.

#### COMAR 10.34.21.04. Duties of a Pharmacist.

- A. The pharmacist shall provide supervision to unlicensed personnel.
- B. The pharmacist may not delegate any pharmacy acts to unlicensed personnel.

On April 24, 2017, the Respondent-Pharmacy, along with their attorney Laurence Russell, Esquire, and Kelly Cooper, Administrative Prosecutor, attended a Case Resolution Conference ("CRC") with members of the Board in an effort to resolve the pending charges in lieu of an evidentiary hearing. As a result of the CRC, the Respondent-Pharmacy and the State agreed to enter into this Consent Order consisting of Findings of Fact, Conclusions of Law, and Order.

## I. FINDINGS OF FACT

The Board finds:

#### I. Background

- 1. At all times relevant, the Respondent-Pharmacy was located in Owings Mills, Maryland.
- 2. On April 28, 2004, the Respondent-Pharmacy was issued a permit to operate a pharmacy in the State of Maryland under Permit No.PW0249.
- The Respondent-Pharmacy's permit is current, and is scheduled to expire on May 31, 2018.
- In a prior case involving the Respondent-Pharmacy (Case Number PI-15-129), on July 6,
   2015, the Board issued a Notice of Deficiencies, Recommended Civil Monetary Penalty,

- and Opportunity for Hearing ("July 2015 Notice"). The Notice alleged that from approximately July 1, 2014 through March 10, 2015, Pharmacy Technician A performed delegated pharmacy acts under a registration that expired on June 30, 2014.
- 5. The July 2015 Notice concluded, as a matter of law, that the Respondent-Pharmacy violated H.O. §§ 12-403(b)(1) and 12-68-01, and recommended the imposition of a civil monetary penalty in the amount of \$1,000.00. Further, the July 2015 Notice provided that if the Respondent-Pharmacy paid the monetary penalty within thirty (30) days, the July 2015 Notice would constitute the Board's final action with respect to the matter.
- 6. On July 23, 2015, the Board received payment of the \$1,000.00 fine.
- 7. On or about August 11, 2015, the Board issued another Notice of Deficiencies, Recommended Civil Monetary Penalty, and Opportunity for Hearing ("August 2015 Notice"). The Notice alleged that on June 11, 2015, the Board conducted an annual inspection of the Respondent-Pharmacy, which revealed deficiencies.
- 8. The Inspection Report revealed that Pharmacy Technician B was performing delegated pharmacy acts under a technician registration that expired on April 30, 2015. Pharmacy Technician B subsequently renewed her registration.
- 9. The August 2015 Notice concluded, as a matter of law, that the Respondent-Pharmacy violated H.O. §§ 12-403(c)(1) and 12-6B-01, and recommended the imposition of a civil monetary penalty in the amount of \$2,000.00. Further, the August 2015 Notice provided that if the Respondent-Pharmacy paid the monetary penalty within thirty (30) days, the August 2015 Notice would constitute the Board's final action with respect to the matter.
- 10. On September 4, 2015, the Board received payment of the \$2,000.00 fine.
- 11. On September 25, 2015, the Board conducted a re-inspection of the Respondent-Pharmacy. During the re-inspection, the inspector again observed two unlicensed

- personnel performing prescription data entry for new and renewal physician orders.
- 12. Based upon the information from the September 25, 2015 re-inspection, on December 8, 2015, the Board issued a Notice of Deficiencies, Recommended Civil Monetary Penalty, and Opportunity for Hearing ("December 2015 Notice"), which recommended the imposition of a civil monetary penalty in the amount of \$5,000.00.
- 13. On December 16, 2015, the Board received a request for a hearing from the Respondent-Pharmacy.
- 14. On February 24, 2016, the Board issued a Finding of Deficiencies and Imposition of Civil Monetary Fine By Consent ("February 2016 Finding"), which concluded as a matter of law, that the Respondent-Pharmacy allowed two unlicensed individuals to perform delegated pharmacy acts without being duly registered as pharmacy technicians or pharmacy technician trainees enrolled in a Board-approved technician training program in violation of H.O. §§ 12-403(c)(1) and 12-6B-01.
- 15. The February 2016 Finding imposed a civil monetary penalty of \$2,500, which was due within thirty (30) days. In the February 2016 Finding, the Respondent-Pharmacy "agreed to revise its policies and procedures to clarify that the Director of Pharmacy is responsible for all pharmacy operations, to include appropriate licensure of staff."
- 16. The Board received payment of the \$2,500 fine.
- 17. On June 3, 2016, the Board conducted an annual inspection on the Respondent-Pharmacy. During the inspection, the following deficiencies were noted:
  - a. An unlicensed individual was on duty and performing job duties such as data entry, processing and billing of prescriptions. According to the Respondent-Pharmacy, the unlicensed individual is a non-renewed pharmacy technician working on continuing education credits to reinstate their registration.

- b. On June 6, 2016, the Board's Inspector received a copy of the payment receipt for reinstatement of the unlicensed individual.
- c. The Board's Inspector found five outdated drug products in the compounding area, although the Respondent-Pharmacy has policies and procedures in place for the removal of expired medication. The five outdates included the following: (1) saran lotion (expired in February, 2016); (2) nystop powder (expired in February, 2009); (3) urea 40% cream (expired in February, 2012); (4) menthol powder (expired in October, 2015); and (5) destin paste (expired in October, 2013).
- 18. The Respondent-Pharmacy's actions, as outlined in pertinent part above, constitute violations of H.O. §§12-403 and/or 12-313(b)(3) and/or 12-313(b)(4), and/or 12-313(b)(25) and/or COMAR 10.34.10.01 and/or COMAR 10.34.21.04.

### II. CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent-Pharmacy violated the following provisions of the Act:

#### § 12-403. Required standards.

- (c) In general Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:
  - (1) Shall be operated in compliance with the law and with the rules and regulations of the Board;
  - (9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under 12-313 or a registered pharmacy technician under 12-6B-09 of this title;
  - (12) Shall store all prescriptions or nonprescription drugs or devices properly and safely subject to the rules and regulations adopted by the Board; [and/or]

(19) May not allow an unauthorized individual to represent that the individual is a pharmacist, a registered pharmacy intern, or registered pharmacy technician[.]

# $\S$ 12-313. Denials, reprimands, suspensions, and revocations—Grounds

- (b) In general Subject to the hearing provisions of § 12-315 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may reprimand any licensee, place any licensee on probation, or suspend or revoke a license of a pharmacist if the licensee:
  - (3) Aids an unauthorized individual to practice pharmacy or to represent that the individual is a pharmacist or a registered pharmacy technician;
  - (4) Delegates pharmacy acts to an unauthorized individual; [and/or]
  - (25) Violates any rule or regulation adopted by the Board[.]

The Board also concludes that the Respondent-Pharmacy violated the following COMAR provisions:

# COMAR 10.34.10.01. Pharmacist Code of Conduct—Patient Safety and Welfare.

#### A. A pharmacist shall:

- (1) Abide by all federal and State laws relating to the practice of pharmacy and the dispensing, distribution, storage, and labeling of drugs and devices, including but not limited to:
  - (a) United States Code. Title 21,
  - (b) Health-General Article, Titles 21 and 22, Annotated Code of Maryland,
  - (c) Health Occupations Article, Title 12, Annotated Code of Maryland,
  - (d) Criminal Law Article, Title 5, Annotated Code of Maryland, and

#### (e) COMAR 10.19.03.

#### B. A pharmacist may not:

- (1) Engage in conduct which departs from the standard of care ordinarily exercised by a pharmacist;
- (2) Practice pharmacy under circumstances or conditions which prevent the proper exercise of professional judgment; or
- (3) Engage in unprofessional conduct.

#### COMAR 10.34.21.04. Duties of a Pharmacist.

- A. The pharmacist shall provide supervision to unlicensed personnel.
- B. The pharmacist may not delegate any pharmacy acts to unlicensed personnel.

## III. ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, it is this day of \_\_\_\_\_\_, 2017, by the affirmative vote of a majority of the members of the Board then serving:

ORDERED that within sixty (60) days from the date the Board executes this Consent Order, the Respondent-Pharmacy shall pay a civil fine in the amount of FOUR THOUSAND (\$4,000.00) DOLLARS, payable by certified check or money order to The Maryland State Board of Pharmacy; and it is further

**ORDERED** that the Respondent-Pharmacy's permit shall be placed on **PROBATION** for a period of at least one (1) year; and it is further

**ORDERED** that within thirty (30) days of the date the Board executes this Consent Order, the Respondent-Pharmacy shall submit revised policies and procedures regarding staff licensing verification, to include the requirement that the Director of Pharmacy has the responsibility to ensure active and appropriate licensing of all staff; and it is further

ORDERED that during the probationary period, the Board, at its discretion, may conduct

random inspections of the Respondent-Pharmacy; and it is further

ORDERED that the Respondent-Pharmacy shall provide the Board with copies of the

registration cards for all pharmacy technicians during the period of probation, within 10 days of

hiring; and be it further

ORDERED that the Respondent-Pharmacy shall not delegate pharmacy acts to an

employee that is unauthorized to perform pharmacy acts, including pharmacy personnel whom

have a non-renewed registration; and it is further

**ORDERED** that the Respondent-Pharmacy shall operate in accordance with the laws and

regulations governing the practice of pharmacy in Maryland; and it is further

**ORDERED** that the Respondent-Pharmacy shall bear the cost(s) of complying with the

Consent Order; and it is further

**ORDERED** that failure to comply with the terms and conditions of the Consent Order,

including failure to pay the monetary fine in full, by the deadline, constitutes a violation of the

Consent Order and the Board, in its discretion, after notice and an opportunity for a show cause

hearing before the Board, may impose any appropriate sanction under the Act; and it is further

**ORDERED** that this Consent Order is considered a **PUBLIC DOCUMENT** pursuant to

Md. Code Ann., Gen. Prov. §§ 4-101 et seq. (2014 Repl. Vol. and 2016 Supp.).

Date

DeenaSpeights-Napata, Executive

Director, for

MitraGavgani, Pharm.D., President

State Board of Pharmacy

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CONSENT

I, Barbara Denrich, owner of Alco Pharmacy, acknowledge that I have had the

opportunity to consult with legal counsel before signing this document. By this Consent, I

accept, on behalf of Alco Pharmacy, to be bound by this Consent Order and its conditions and

restrictions. On its behalf, I waive any rights Alco Pharmacy may have had to contest the

Findings of Fact and Conclusions of Law.

I acknowledge the validity of this Consent Order as if entered into after the conclusion of

a formal evidentiary hearing in which Alco Pharmacy would have had the right to counsel, to

confront witnesses, to give testimony, to call witnesses on its behalf and to all other substantive

and procedural protections as provided by law.

I acknowledge the legal authority and the jurisdiction of the Board to initiate these

proceedings and to issue and enforce this Consent Order. I also affirm that I am waiving Alco

Pharmacy's right to appeal any adverse ruling of the Board that might have followed any such

hearing.

I sign this Consent Order without reservation, and I fully understand and comprehend the

language, meaning and terms of this Consent Order. I voluntarily sign this Order on behalf of

Alco Pharmacy and understand its meaning and effect.

S 24/17

Barbara Denrich, Owner

Alco Pharmacy

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# **NOTARY**

STATE OF
COUNTY/CITY OF: Barring
I hereby certify that on this 24 day of, 2017, before me, a Notary
Public of the State of and County/City aforesaid, personally appeared
BARBARA DENRICH, and made an oath in due form that the foregoing Consent was her
voluntary act and deed.
AS WITNESSETH my hand and notarial seal.
Notary Public  Notary Public  NOTAP  NOTAP  NOTAP  My Commission Expires: 8-26-19
My Commission Expires: 8.20.13